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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,179	06/29/2000	Yuan Chang	45185-CA/JPW/SHS	1263
7590	09/16/2004		EXAMINER LAMBERTSON, DAVID A	
John P White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/607,179

Applicant(s)

CHANG ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed June 25, 2004.

Amendments were made to the claims.

Claims 52 and 53 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed March 22, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 and 53 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

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Claims 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 112***

Applicant's arguments filed June 25, 2004 have been fully considered but they are not persuasive. Concerning the rejection under Written Description, the following grounds of traversal are presented:

1. It is argued that "it would be routine to identify a large number of such  $\geq 30$ -nt sequences from the nucleotide sequence of SEQ ID NO: 14, based on the specification," and that by using tools in the prior art, "one skilled in the art could easily determine which peptides encoded by such  $\geq 30$ -nt sequences uniquely define a herpesvirus associated with Kaposi's sarcoma" (see for example page 6, the top of the third paragraph of Applicant's response).
2. It is asserted that the provision of the complete nucleotide sequence of SEQ ID NO: 14 is sufficient disclosure of a relevant identifying characteristic, i.e., structure, to show that applicant's were in possession of the claimed genus" (see for example page 6, the bottom of the third paragraph of Applicant's response).
3. It is argued that the prior art discloses homology search tools such as BLAST, which overcome the deficiencies in the description of the claimed invention. Therefore, the Office's statement that the prior art does not provide teachings regarding sequences within SEQ ID NO:

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14 that are unique to a herpes virus associated with Kaposi's sarcoma are without merit (see for example page 7, top paragraph of Applicant's response).

Applicant's arguments have been fully considered, but are not found convincing for the following reasons:

1. The ability for the skilled artisan to identify  $\geq 30$ -nt sequences of SEQ ID NO: 14 that uniquely define a herpesvirus associated with Kaposi's sarcoma is not the issue that is raised in a Written Description rejection. It is not the standard for Written Description that the invention must be identifiable, but rather that it must be described. By definition, if the skilled artisan must identify the sequences that are claimed, the sequences cannot be described; otherwise there would be no need to identify these sequences. What has been described is SEQ ID NO: 14; there is no description of which sub-sequences meet the functional limit of being "unique" to a herpesvirus associated with Kaposi's Sarcoma. As such, Applicant's argument that the sequences could be identified does not indicate that those sequences were described, and the arguments cannot overcome the rejection.
2. What is described in the instant specification with regard to the claims is SEQ ID NO: 14 (and there is not even an assertion that this sequence is "unique"); however, this does not mean that all "unique" polypeptides encoded by sub-sequences/fragments within SEQ ID NO: 14 are described, as Applicant suggests. Merriam-Webster defines "unique" as "being the only one." Thus, the inclusion of the term "unique" in the claim confers a functional limitation on the claimed sequences whereby no claimed sequence can exist anywhere else, ever. This is not a question of novelty at the time of filing; in order for something to maintain the functional characterization of "unique," it must never be duplicated.

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For instance, at the time of filing, the skilled artisan might guess that any such polypeptide encoded by any portion of SEQ ID NO: 14 was “unique,” there being no guidance in the specification to dictate which potential polypeptides were or were not unique. The skilled artisan might choose the polypeptide corresponding to amino acids 257-266 (YLEGVMGVGK) of the protein encoded by SEQ ID NO: 14. While at the time of filing, the sequence met the functional limitation of being “unique,” an identical polypeptide was later identified within a rhesus macaque rhadinovirus (see for example Searles *et al.*, *J. Virol.* **73**: 3040-3053, 1999; see specifically the EMBL entry AF083501, more specifically sub-entry AAD21347.1). This new sequence, while not undermining the novelty of the sequence, does undermine its “uniqueness.” A similar situation exists for the polypeptide corresponding to amino acids 263-272 (GVGKSTLVNA) of the protein encoded by SEQ ID NO: 14. At the time of filing, the sequence met the functional limitation of being “unique.” However, an identical polypeptide was later identified within a *V. parahaemolyticus* genome (see for example Makino *et al.*, *Lancet* **361**: 743-749, 2003; see entire document, specifically the EMBL entry AP005089, more specifically sub-entry BAC62972.1). The instant specification does not describe what other potential polypeptides have a structure (i.e., a sequence) that will necessarily meet the functional limitation of being “unique.” It should be clear that this is NOT an art issue, but rather an issue of meeting the functional limitation of “unique,” and how the instant specification does not describe structural elements (i.e., sequences) that meet the functional limitation.

The point here is that the skilled has no idea as to what is being claimed in the instant claims. This is because there is no distinct description as to what polypeptides meet the limitation of being “unique.” While at the time of filing the aforementioned polypeptides would

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have fit within the boundaries of the claimed invention, it is clear that they no longer meet the limitation of being "unique" and can longer be claimed. Thus, with regard to the claims at hand, there is no description of what peptides will have a specific structure that necessarily meets the limitation of being "unique" (as opposed to novel).

3. The BLAST program in and of itself does not describe anything regarding the protein encoded by SEQ ID NO: 14. Thus, it cannot satisfy a description of "unique" polypeptides encoded by SEQ ID NO: 14. Furthermore, it is reiterated that the ability to identify a protein that falls within the scope of the claim does not satisfy that protein having been described in terms of a structure-function relationship.

In conclusion, one cannot rely on the ability to identify a polypeptide as "unique" in order to meet the written description requirement. If a polypeptide must be identified, then it cannot be described in terms of a structure-function relationship. Furthermore, even if a particular polypeptide was selected and determined to be "unique" at a particular time (for example, the time of filing), this does not satisfy the functional limitation of being "unique." This is demonstrated above where particular polypeptides encoded by SEQ ID NO: 14 were "unique" at the time of following, but no longer meet the functional limitation of being "unique." As such, the Written Description rejection is maintained.

Applicant's arguments filed June 25, 2004 have been fully considered but they are not persuasive. Concerning the rejection under Enablement, the following grounds of traversal are presented:

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1. It is again argued that the skilled artisan would be able to readily identify peptides encoded by fragments of SEQ ID NO: 14 that are unique to a herpesvirus associated with Kaposi's sarcoma (see for example page 9, the last paragraph of Applicant's response).
2. It is asserted that the "mere possibility of the existence of an unidentified nucleic acid sequence cannot be used to deny the demonstrated uniqueness of any given sequence" (see for example page 10, the second paragraph of Applicant's response).

Applicant's arguments have been fully considered, but are not found convincing for the following reasons:

1. Similar to the Written Description rejection, the ability to identify a polypeptide is not the standard for meeting the Enablement requirement. In order for the Enablement requirement to be met, the skilled artisan must be able to make and use the claimed invention. However, if the invention has yet to be identified, one of skill cannot make the invention. Thus, Applicant's arguments are not convincing.
2. Contrary to the assertion that the "mere possibility of the existence of an unidentified nucleic acid sequence cannot be used to deny the demonstrated uniqueness of any given sequence," the Office has demonstrated that the uniqueness of any sequence can be questioned. This is clear from the fact that at least two polypeptides of 10 amino acids or longer (both of which are within the protein encoded by SEQ ID NO: 14) undermine the functional limitation of "unique" in the instant case. Because the instant claims have been written to include the functional limitation "unique," the claims must meet that limitation in terms of enablement. That means that the skilled artisan must be able to make a polypeptide encoded by SEQ ID NO: 14 that maintains its "uniqueness." However, this cannot be done in the instant case, because the skilled artisan



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cannot make a protein that is necessarily “unique” evidenced by the examples presented above in the response to arguments concerning the Written Description rejection. This is because there is no guidance in the specification as to which polypeptides are considered “unique,” and the prior art provides no information on the subject.

In conclusion, it is again asserted that the ability to identify a polypeptide does not satisfy the enablement requirement of “to make and use.” Furthermore, it is asserted that identifying a polypeptide that is “unique” at one point in time does not necessarily meet the limitation of unique. This is because that polypeptide may be present in another polypeptide that, upon its sequencing, negates the functional ability of the polypeptide to meet the limitations of the claim. Indeed, this is already true in the instant case concerning at least the polypeptides YLEGVMGVGK and GVGKSTLVNA (which are encoded by sub-sequences/fragments within SEQ ID NO: 14). These polypeptides cannot be considered to meet the limitations of the instant claims because they have been found in a non-herpesvirus associated with Kaposi’s sarcoma. Thus, the skilled artisan would be left to question which polypeptides can be made that do meet the limitations of the claimed invention, given the limited guidance provided by both the instant specification and the state of the art.

*Allowable Subject Matter*

No claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.  
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JAMES KETTER  
PRIMARY EXAMINER